

## **REMARKS**

Claims 1-35 are pending and stand rejected as final. Applicants have amended claims 1, 3, 7, 8, 30, and 34. Applicants furthermore have canceled claim 35 without prejudice or disclaimer to the subject matter claimed therein. Reconsideration of the rejection is respectfully requested in view of these amendments and the following remarks.

Applicants respectfully submit that support for the amendments to claims 1, 30 and 34 can be found in the instant specification at, for example, in the paragraph bridging pages 2 and 3; page 6, lines 23-26; page 45, lines 8-10, as well as claim 1 as originally presented.

### **Claim Rejections - 35 USC §102**

Claims 1-9, 17-19, 22-26, and 30-35 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,948,540 to Nigam (hereinafter referred to as "Nigam"). Applicants respectfully traverse this rejection.

Applicants respectfully submit that Nigam neither discloses nor suggests the claimed invention. Specifically, the material of Nigam does not have a paste consistency. Applicants respectfully submit that the claimed paste consistency is important for being able to move the implant endoscopically to the tissue defect site to be repaired, for example, with a syringe-type device, place it in the defect site, and yet have the implant be sufficiently viscous that it will not pour out or fall out of the site under its own weight.

Further, Nigam is not an implant, but instead is topical, i.e., a wound dressing sheet material.

Still further, the claimed invention is tissue conductive. In contrast, there is nothing in Nigam to suggest that his dressing sheet material is tissue conductive or otherwise promotes tissue ingrowth.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

Claims 1, 2, and 4-28 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,425,769 to Snyders, Jr. (hereinafter referred to as "Snyders"). Applicants respectfully traverse this rejection.

Applicants respectfully submit that Snyders neither discloses nor suggests the claimed invention, which is directed to an implant that remains at least somewhat compliant following implantation. In contrast, the implant of Snyders loosely mimics the structure of human bone by immobilizing a fibrous collagen in a calcium sulfate matrix. More specifically, Snyders states that "The mineralized collagen fiber network imparts tensile and fatigue strength to the otherwise brittle mineral matrix, while the calcium sulfate imparts compressive strength and morphologic stability to the otherwise excessively compliant organic material." In other words, Snyders considers collagen fibers by themselves as being excessively compliant. The

ability of the claimed implant to remain at least somewhat compliant after implantation is important because such an implant can be used where articulation of the tissue under repair is desirable, or where compliance-matching of adjacent tissue is advantageous.

The Action notes that the implant of Snyders has a paste consistency. However, this is prior to implantation. After implantation, his implant “sets up” or solidifies to mimic bone material. Specifically, Snyders states: “The composition is prepared in a method of formulating a resorbable material by immobilizing a collagen material having mechanical strength characteristics within a calcium sulfate material and subjecting the composition to a hydration reaction which passes through a fluid state to a moldable state and to a **solid**.” (See the Abstract, for example.)

Still further, Snyders seems to lack the claimed soluble biocompatible component. To the extent Snyder’s collagen is soluble, then seemingly he is lacking the claimed insoluble fibrous component.

The Action characterizes Snyders as “comprising a matrix, a binder/carrier and a ceramic. Said matrix comprises collagen fibers. Said binder can act as porosifying/foaming agent.” In response, Applicants cannot locate these terms “matrix” and “porosifying/foaming agent” in the places cited. Applicants’ understanding of Snyders is that it is a composite of collagen fibers and plaster intended to mimic natural bone (col. 5, lines 26-29). The composite can carry a variety of alloplastic, allogeneous or autologous materials, or biochemical agents (col. 6, lines 44-57). These agents may be loaded into polylactic acid or polyglycolic acid capsules, which are incorporated into the matrix of the composite. Or, they may simply be carried by the plaster component itself (col. 6, lines 46-59).

In sum, Snyders tries to mimic natural bone by creating a rigid or solid plaster-based implant. In contrast, the claimed invention is not rigid like cured plaster, but instead remains at least somewhat compliant after implantation.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

Claims 1-14, 17-19, 22-28, 30, 34 and 35 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,110,484 to Sierra (hereinafter referred to as “Sierra”). Applicants respectfully traverse this rejection.

Applicants respectfully submit that Sierra neither discloses nor suggests the claimed implant, which is directed in part to remaining “at least somewhat compliant” following implantation. In contrast, Sierra discloses an implant that “is capable of solidifying when being cast or of solidifying and polymerizing in situ.” (See, for example, col. 3, lines 65-66.) As with Snyders, **solidifying** is inconsistent with the claimed invention.

Further on this point, Sierra discloses an implant that has a “stiffness modulus” (see, for example, col. 6, lines 43-55). Applicants respectfully submit that the phrase “stiffness modulus”, sometimes referred to as “elastic modulus”, is meaningless and would not be used

in connection with substances that are viscous, e.g., can flow under application of shear force. Rather, this term refers to substances that are not flowing or not plastically deforming under applied loads, but instead are responding to the load in a purely elastic manner.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

Claims 1-35 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Publication US2002/0183855 to Yamamoto et al. (hereinafter referred to as "Yamamoto"). Applicants respectfully traverse this rejection.

Applicants respectfully submit that Yamamoto neither discloses nor suggests the claimed invention. The implant of Yamamoto has shape memory (see, for example, Paragraphs [0031] and [0034]). In contrast, the claimed implant has a paste consistency.

The Action stated that "the Yamamoto matrix comprises the same materials as Applicants' matrix, using the same ratios and consistency, and intended for the same purpose(s). The results will inherently be the same." Applicants respectfully disagree with this statement.

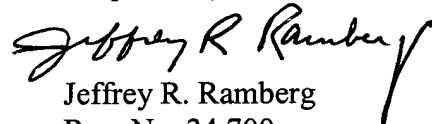
The claimed invention is compositionally different from Yamamoto. Among the differences is that Yamamoto mineralizes his matrix by stirring insoluble collagen fibrils in a reactor containing calcium chloride and tribasic sodium phosphate maintained at a pH of about 11. In contrast, the fibers of the claimed invention are not mineralized in the way described by Yamamoto.

Accordingly, applicants respectfully request that this rejection be withdrawn.

In view of the above amendments and remarks, Applicants respectfully submit that the present application is in condition for allowance. Accordingly, Applicants respectfully request issuance of a Notice of Allowance directed to claims 1-34.

Should the Examiner deem that any further action on the part of Applicants would be desirable, the Examiner is invited to telephone Applicants' undersigned representative.

Respectfully submitted,



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